To The Point
An Introduction to FDA Form 483

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The Food and Drug Administration (FDA) has powers to audit domestic and international sites involved in manufacturing or distributing any food, drug, device or cosmetic imported into or used in the USA. Chubb's Risk Engineers trained in Life Sciences can help companies benchmark effective risk management programs and support proactive processes around loss prevention.

Identifying Compliance Violations

A Form 483 is a document issued by the FDA to company management when auditors observe any condition that, in their judgment, may constitute a violation of the Food, Drug, and Cosmetic Act (FD&C) or related acts. It is a type of regulatory citation.

Generally, the document reviews the adverse condition, what should be done to remedy the situation, and in what time span. According to the FDA, "Observations are made when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health."[1]

Once received, the company management must produce a formal or written corrective action plan to remedy the adverse conditions within the timescale given. Inadequate responses to the FDA 483s can result in further enforcement, including issuing Warning Letters, which are less common but published weekly on the FDA website.[2]

Risks and Repercussions

The FDA has significant enforcement authority and can insist on stopping or modifying a process with legal tools, including injunctions and consent decrees.

An injunction[3] is a legal tool used by the FDA to enforce compliance with the laws and regulations pertaining to the safety and efficacy of food, drugs, medical devices, cosmetics, and other regulated products. It is a court order that restricts or prohibits specified activities until

certain conditions are met. This can lead to the complete shutdown of a site until the issues are resolved.

A consent decree[3] is a legal agreement between the FDA and a company that resolves a case involving violating the regulations. It is typically entered into when the FDA has serious concerns about a company's compliance with applicable laws and regulations and aims to ensure future compliance with strict oversight. Once approved, the company must comply with the terms, and the FDA closely monitors the company's compliance with additional inspections and other actions. For any additional questions about the FDA's legal process, seek guidance from internal counsel.

Beyond the financial implications of loss of revenue, there is also a broader issue that can directly affect life sciences companies. The FDA findings are published and can be reviewed by the public.

Open 483s and warning letters could motivate plaintiff attorneys to investigate further patient adverse events (illness, injuries, or product issues associated with life sciences products) and provide a pathway for identifying potential plaintiffs allegedly harmed by these products. Once in litigation, 483s and warning letters could become factors that may lessen a company's defense if evidence of their product causing harm can be linked.

Audit Results and Compliance Dashboard

The Compliance Dashboard[4] on the FDA website provides an overview of audit results. It should be noted that the FDA has categories of inspection findings, which include:

- NAI – No Action Indicated (no issues identified)
- VAI – Voluntary Action Indicated (issues were found that could rise to the level of a formal Form 483)
- OAI – Official Action Indicated (significant issues that would be found in 483s and warning letters)

The data can be filtered to show only the search terms if searching for a specific company name. Details on the Compliance Dashboard include:

- The number of FDA inspections per year
- The nature of the top ten citations
- A long description of the nature of the Form 483 citations

The following are key factors to understand when reviewing FDA audits and audit results:

- Note the site's last FDA audit.
- Check key findings, the number of Form 483 observations issued, and if any are related to product quality or patient safety.
- Determine if there is a history of repeated citations for the same issue.
- Examine the site's actions taken to complete the Form 483 requirements. If available, the site's written response to the 483 will provide context and concrete steps to ensure compliance with the issue.

How Chubb Can Help

483s and Warning Letters document violations of FDA regulations. The recipient must take prompt action to rectify the identified issues. Despite prompt action, these regulatory citations may draw unwanted attention to a life sciences company and lessen its product liability defenses.

It is important for companies to work proactively and openly with the FDA and other regulatory bodies to avoid any regulatory issues from occurring. Working with an insurance carrier like Chubb with Risk Engineers trained in Life Sciences[5] can be very helpful to provide benchmarking on product liability risk management programs. Our experienced professionals help companies of all sizes and industries identify and minimize potential losses.

References

U.S. Food & Drug Administration (FDA)

1. Frequently Asked Questions, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions
2. Warning Letters, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters
3. Regulatory Procedures Manual, https://www.fda.gov/media/71837/download
4. Inspections, https://datadashboard.fda.gov/ora/cd/inspections.htm

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5. Risk Engineers Trained in Life Sciences, https://www.chubb.com/us-en/business-insurance/life-sciences-risk-engineering.html

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